

## CHLORPYRIFOS TECHNICAL BRIEFING

June 8, 2000

## Overview

Lois Rossi, Director  
Special Review and Reregistration Division  
OPP

## Overview of Day's Activities

- ❖ Legal framework and regulatory history
- ❖ Provide usage profiles
- ❖ Present risk assessments
- ❖ Questions and comments

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## Goals of Meeting

- ❖ Provide an understanding of EPA's risk assessments
- ❖ Answer your questions
- ❖ Identify risks of concern
- ❖ Begin risk mitigation dialog

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## Legal Context

FQPA amendments to FIFRA required

- ❖ Reassessment of all existing tolerances
- ❖ Aggregate assessments
- ❖ Safety factor for children
- ❖ Cumulative assessments

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## EPA Implementation of FQPA

- ❖ Formation of Tolerance Reassessment Advisory Committee (TRAC)
- ❖ Development of science policies
- ❖ Development of pilot process for public participation
- ❖ Focus on OPs

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## TRAC Pilot OP Review Process

- ❖ Phase 1 (30 days)
  - ◆ Registrant "error only" review
- ❖ Phase 2 (up to 30 days)
  - ◆ EPA considers registrants' comments
- ❖ Phase 3 (60 days)
  - ◆ Public comment on preliminary risk assessment

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## TRAC Pilot OP Review Process (cont.d)

- ❖ Phase 4 (90 days)
  - ◆ EPA revises risk assessments, holds public meetings/technical briefings
- ❖ Phase 5 (60 days)
  - ◆ EPA solicits risk management ideas
- ❖ Phase 6 (up to 60 days)
  - ◆ EPA develops final risk management strategies

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## Agreement with Registrants

- ❖ Agency had discussions with Dow, and other technical and MUP registrants
- ❖ Achieved agreement that addresses risk of concern
- ❖ Public participation will allow comments
  - ◆ Focus on remaining issues – worker and ecological risk mitigation
  - ◆ 6f process for cancelled uses

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## Summary of Agreement

- ❖ For Agricultural Uses
  - ◆ Restrict apples to pre-bloom
  - ◆ Remove use on tomatoes

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## Summary of Agreement

- ❖ For Residential Non-Termiticide Uses
  - ◆ All uses removed except golf courses, containerized baits, and two public health uses (mosquitocide and fire ant)
- ❖ For Other Non-Termiticide Uses
  - ◆ All uses removed except limited use in industrial settings

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## Summary of Agreement

- ❖ For Termiticide Uses
  - ◆ Whole house post-construction removed
  - ◆ Limited spot and local post-construction phased out (by 2002)
  - ◆ Pre-construction phased out (by 2005)

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## Regulatory History and Comments

Mark Hartman, Chemical Review Manager  
Special Review and Reregistration Division  
OPP

## Regulatory History

- ❖ First registered in 1965 by Dow Chemical Company
- ❖ Registrants are:
  - ◆ DowAgroSciences
  - ◆ Mahketshim-Agan
  - ◆ Gharda
  - ◆ Cheminova
  - ◆ Luxembourg-Pamol
  - ◆ Platte Chemical
- ❖ Registration Standards issued in 1984 and 1989

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## Phase 3 Public Comment

- ❖ Over 4,000 comments received
- ❖ Comments received from:
  - ◆ Registrants
  - ◆ Environmental/Consumer Organizations
  - ◆ Commodity Associations
  - ◆ Extension Personnel
  - ◆ Government Officials
  - ◆ Growers
  - ◆ Retailers
  - ◆ Crop Consultants
  - ◆ Pest Control Operators
  - ◆ Lawn Care Professionals
  - ◆ Golf course superintendents
  - ◆ Private Citizens

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## Environmental and Consumer Comments

- ❖ Common mechanisms of toxicity
- ❖ FQPA 10X Safety Factor
- ❖ Highly exposed populations
- ❖ Data requirements/assumptions
- ❖ Transitioning to safer alternatives
- ❖ Incidents/Illnesses
- ❖ TCP

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## Registrant Comments

- ❖ Toxicological Endpoint Selection
- ❖ FQPA Safety Factor Determination
- ❖ Ecological Assessment

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## User Community Comments

- ❖ Importance to IPM programs
- ❖ Effectiveness and economics
- ❖ Lack of equivalent alternatives
- ❖ Use of processing factors in dietary analysis

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## Phase 4 Revise Risk Assessments

- ❖ Changes to the risk assessment
  - ◆ Refined dietary assessment
  - ◆ Revised worker assessment
  - ◆ Revised residential assessment
  - ◆ Revised ecological assessment

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## Phase 5

- ❖ Technical briefing
- ❖ Revised risk assessment (incorporating all studies) available in public docket and on the internet
- ❖ Begin 60-day public participation period
- ❖ Public input on risk management
- ❖ Opportunities for growers and other to meet with EPA

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## CHLORPYRIFOS Use Profile

Tim Kiely, Economist  
Biological and Economic Analysis Division  
OPP

## Use Profile

- ❖ Organophosphate  
Insecticide/Acaricide/Nematicide
- ❖ Currently Not a Restricted Use
- ❖ 12 Formulation of End Use Products
  - ◆ 827 Active Labels

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## Use Profile

❖ End Use Products	% AI
◆ Emulsifiable Concentrate	0.25 – 62.5
◆ Soluble Concentrate/Liquid	0.5 – 62.5
◆ Wettable Powder	25 - 50
◆ Water Dispersible Granules	50
◆ Granular	0.14 – 15.3
◆ Flowable Concentrate	30
◆ Microencapsulated	0.2 – 20
◆ Liquid-Ready to Use	0.05 – 17.4
◆ Pressurized Liquid	0.1 – 8
◆ Bait/Solid	0.3 – 1
◆ Dust	0.5 – 7
◆ Impregnated Material/Collar/Tag	3 – 20

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## Use Profile

- ❖ 358 Use Sites
  - ◆ Agricultural Uses
    - Field Crops
      - Corn, sorghum, tobacco, wheat, alfalfa, peanuts, soybeans, sunflower, cotton, sugar beets, mint, lentils, rice, sugarcane
    - Vegetables
      - Onions, peppers, kale, broccoli, brussel sprouts, cabbage, cauliflower, collards, cucurbits, asparagus, tomatoes, beans, peas, chinese cabbage, kohlrabi, broccoli raab, sweet corn, carrots, radish, rutabaga, turnip, sweet potatoes
    - Fruit
      - Citrus, apples, figs, prunes, pears, nectarines, cherries, peaches, plums, grapes, strawberries, bananas, cranberries
    - Nut Trees
      - Almonds, pecans, walnuts, chestnuts, filberts, macadamias

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## Use Profile

- ◆ Residential Uses
  - Lawn and Turf
  - Ornamentals
  - Structural (Termiticide)
  - Pets
- ◆ Public Health (i.e., Mosquito Control) and Quarantine (i.e., Fire Ant Control) Uses
- ◆ Other
  - Livestock
  - Food Handling Establishments
  - Forestry

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## Use Profile

- ❖ Application Method (list only representative)
  - ◆ Soil Treatment (banded, rodded, in-furrow, mound, etc.)
  - ◆ Spray (low volume, high volume, surface, foliar, etc.)
  - ◆ Seed Treatment
  - ◆ Tree Bark Treatment
  - ◆ Crack and Crevice Treatment
  - ◆ Perimeter Treatment

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## Use Profile

- ❖ Application Equipment (list is only representative)
  - ◆ Airblast Sprayer
  - ◆ Groundboom Sprayer
  - ◆ Aerial Sprayer
  - ◆ Tractor-drawn Granular Spreader
  - ◆ Hand-held Sprayers (LP Handwand, HP Handwand, Hose-end Sprayer, etc.)
  - ◆ Aerosol Can
  - ◆ Push-type Spreaders

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## Use Profile

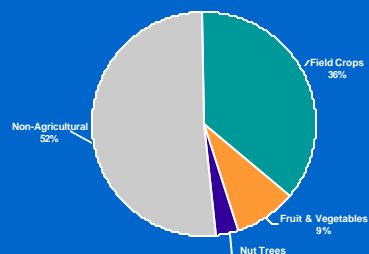
- ❖ Average Agricultural Use Rates
  - ◆ Most acreage treated at a rate of 2 lbs/ai or less per application
  - ◆ Most acreage treated at 4 lbs/ai or less per year
- ❖ Typical Usage
  - ◆ Estimated 21 million lbs ai applied annually to all sites
    - Largest agricultural market is corn at 26% of total lbs applied
    - No other crop accounts for >3% of total lbs applied
    - Largest non-agricultural markets are PCO Termite Control (24%) and Professional Turf (12%)
  - ◆ Agricultural sites – 10 million lbs ai applied
  - ◆ Non-Agricultural sites – 11 million lbs ai applied

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## Use Profile

Chlorpyrifos Usage  
As a % of Total lbs Applied  
In Agricultural and Non-Agricultural Markets



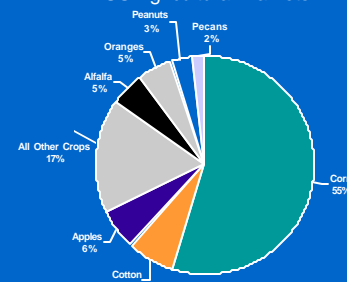
Source: EPA Data  
Estimated 21 million lbs applied

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## Use Profile

Chlorpyrifos Usage  
As a % of Total lbs Applied  
In US Agricultural Markets



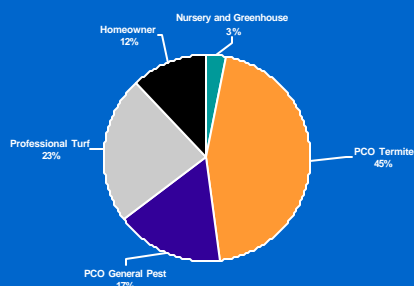
Source: EPA Data  
Estimated 10 million lbs Applied

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## Use Profile

Chlorpyrifos Usage  
As a % of Total lbs Applied  
In US Non-Agricultural Markets



Source: EPA data  
Estimated 11 million lbs Applied

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## Use Profile

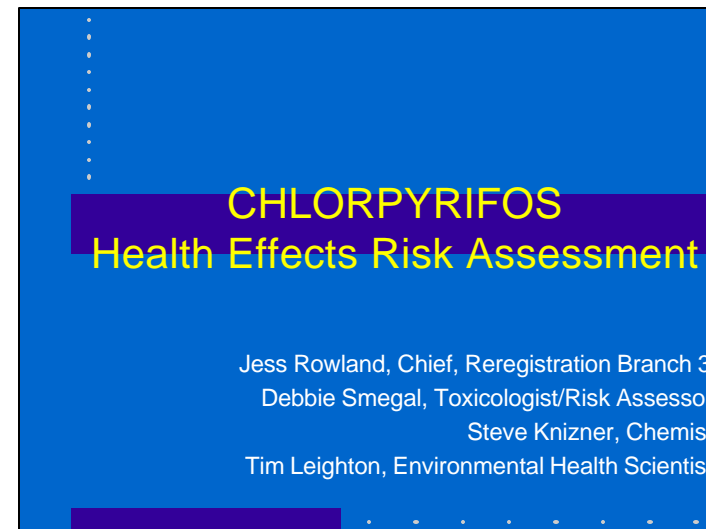
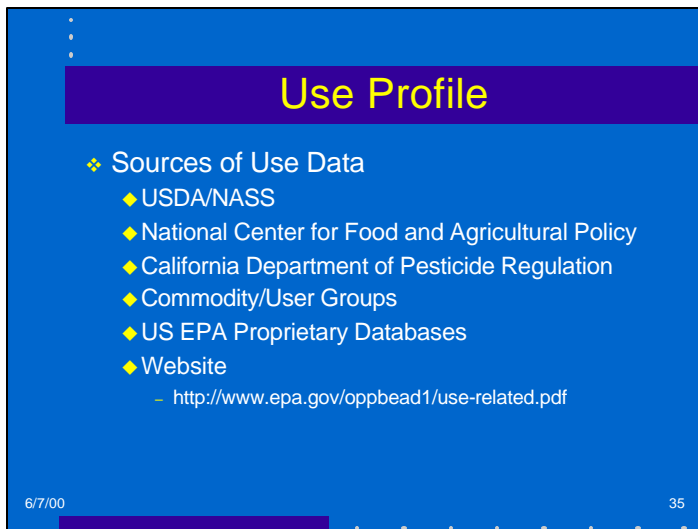
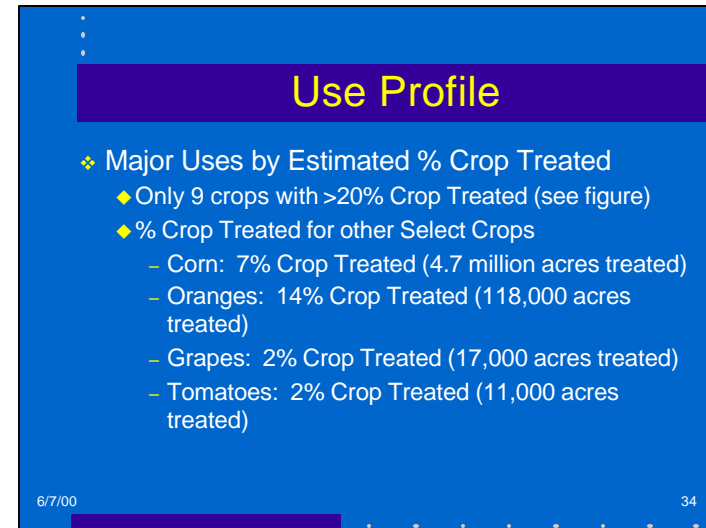
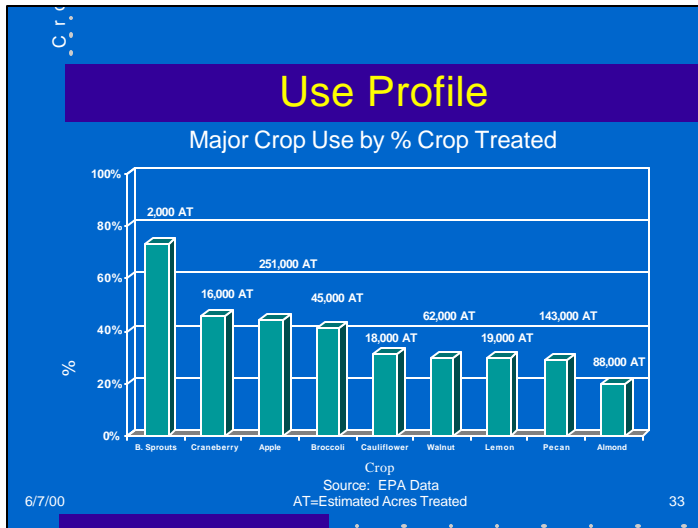
### ❖ Major Uses by Estimated % Crop Treated

- ♦ Only 9 crops with >20% Crop Treated (see figure)
- ♦ % Crop Treated for other Select Crops
  - Corn: 7% Crop Treated (4.7 million acres treated)
  - Oranges: 14% Crop Treated (118,000 acres treated)
  - Grapes: 2% Crop Treated (17,000 acres treated)
  - Tomatoes: 2% Crop Treated (11,000 acres treated)

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## Risk Assessment Components

- ❖ Dietary
  - ◆ Food
  - ◆ Drinking Water
- ❖ Occupational (Agricultural Workers)
- ❖ Residential
  - ◆ Handlers
  - ◆ Post Application
- ❖ Aggregate
  - ◆ Food
  - ◆ Drinking Water
  - ◆ Residential

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## Hazard Identification Process

- ❖ Weight of evidence approach
- ❖ Review/evaluation of all toxicology studies
- ❖ Select studies appropriate for route and duration of exposure scenario

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## Hazard Identification Process

- ❖ Consider all adverse effects seen – species/sex/route/duration
- ❖ Select critical endpoint of concern
- ❖ Select the dose for the critical effect
- ❖ Critical toxic effect (endpoint) selected would be protective of all potential toxic effects

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## Effect Levels

- ❖ Lowest Observed Adverse Effect Level = LOAEL
  - ◆ The lowest dose at which an “adverse” health effect is seen (mg per kg body weight per day)
- ❖ No Observed Adverse Effect Level = NOAEL
  - ◆ The dose at which no “adverse” health effect is seen. This dose is less than the LOAEL (mg per kg body weight per day)

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## Uncertainty and Safety Factors

- ❖ 10X Interspecies Extrapolation
  - ❖ 10X Intraspecies Variation
  - ❖ 1X to 10X FQPA Safety Factor
- 
- ❖ 100X to 1000X Total Uncertainty and Safety Factors for Risk Assessment

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## CHLORPYRIFOS Hazard Identification for Dietary and Non-Dietary Risk Assessments

## Acute Hazard (Toxicity)

- ❖ **Studies:** Two acute (single dose) studies
- ❖ **Endpoint**
  - ◆ Plasma and RBC cholinesterase inhibition
- ❖ **NOAEL:** 0.5 mg/kg/day
- ❖ **LOAEL:** 1.0-1.5 mg/kg/day

*Endpoint reflects the potential toxicity which could result from one-day exposure to chlorpyrifos*

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## Chronic Hazard (Toxicity)

- ❖ **Studies:** Weight of Evidence using 5 studies
- ❖ **Endpoint**
  - ◆ Plasma and RBC cholinesterase inhibition
- ❖ **NOAEL:** 0.03 mg/kg/day
- ❖ **LOAEL:** 0.22-0.3 mg/kg/day

*Endpoint reflects the potential toxicity which could result from long-term exposure to chlorpyrifos*

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## Analysis of Sensitivity/Susceptibility of the Young (FQPA Safety Factor)

### Rationale for Retaining 10X Factor

- ◆ Increased neonatal sensitivity following a low single oral exposure
- ◆ Unique susceptibility of the offspring demonstrated in the DNT study
- ◆ The adverse effects on brain development may occur in the absence of ChE inhibition
- ◆ Lack of an offspring NOAEL for alterations in brain development – DNT

### 10X is Applied To – Infants/Children/Females of Child Bearing Age

- ◆ Acute and chronic dietary exposures
- ◆ All residential/non-occupational exposures

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## Uncertainty Factors

- ❖ 10X Interspecies Extrapolation
- ❖ 10X Interspecies Variation
- ❖ 10X FQPA Safety Factor

### Total UF Applied:

- ❖ General Population: 100
- ❖ Infants and Children: 1000
- ❖ Females of Child Bearing Age: 1000

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## Expression of Risk

### Dietary Exposure

$$RfD = \frac{NOAEL}{UF}$$

RfD = Reference Dose  
PAD = Population Adjusted Dose  
(less than 100% PAD is not concern)

$$PAD = \frac{RfD}{FQPA \text{ Safety Factor}}$$

$$\% \text{ PAD} = \frac{\text{Exposure}}{PAD} \times 100$$

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## Population Adjusted Dose (PAD)

### Acute PAD

#### General Population

$$RfD = \frac{0.5 \text{ mg/kg/day}}{100 \text{ UF}} = 0.005 \text{ mg/kg/day}$$

$$aPAD = \frac{RfD}{1 \text{ FQPA SF}} = \frac{0.005 \text{ mg/kg/day}}{1} = 0.005 \text{ mg/kg/day}$$

#### Children and Females of the Child Bearing Age

$$RfD = \frac{0.5 \text{ mg/kg/day}}{100} = 0.005 \text{ mg/kg/day}$$

$$aPAD = \frac{RfD}{10 \text{ FQPA SF}} = \frac{0.005 \text{ mg/kg/day}}{10} = 0.0005 \text{ mg/kg/day}$$

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## Population Adjusted Dose (PAD)

### Chronic PAD

#### General Population

$$RfD = \frac{0.03 \text{ mg/kg/day}}{100 \text{ UF}} = 0.0003 \text{ mg/kg/day}$$

$$cPAD = \frac{RfD}{1 \text{ FQPA SF}} = \frac{0.0003 \text{ mg/kg/day}}{1} = 0.0003 \text{ mg/kg/day}$$

#### Children and Females of the Child Bearing Age

$$RfD = \frac{0.03 \text{ mg/kg/day}}{100 \text{ UF}} = 0.0003 \text{ mg/kg/day}$$

$$cPAD = \frac{RfD}{10 \text{ FQPA SF}} = \frac{0.0003 \text{ mg/kg/day}}{10} = 0.00003 \text{ mg/kg/day}$$

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## Expression of Occupational/Residential Risk

$$MOE = \frac{NOAEL}{\text{Exposure}}$$

- ❖ MOE: Margin of Exposure
- ❖ Target MOE: 100 (occupational)  
1000 (residential)
- ❖ The larger the MOE, the lesser the concern

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## Occupational/Residential Risk Assessment - Dermal

- ❖ Short-term exposure
  - ◆ **Study:** 21-day dermal – rat
  - ◆ **Endpoint:** Plasma and RBC cholinesterase inhibition
  - ◆ **NOAEL:** 5 mg/kg/day
  - ◆ **LOAEL:** 10 mg/kg/day
  - ◆ **Target MOE:** 100 (occupational)  
1000 (residential)\*

\* Includes the 10X FQPA Safety Factor

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## Occupational/Residential Risk Assessment - Dermal

- ❖ Intermediate and long-term exposure
  - ◆ **Study:** Weight of Evidence using 5 studies
  - ◆ **Endpoint:** Plasma and RBC cholinesterase inhibition
  - ◆ **NOAEL:** 0.03 mg/kg/day
  - ◆ **LOAEL:** 0.22 mg/kg/day
  - ◆ **Dermal absorption:** 3% (oral equivalent)
  - ◆ **Target MOE:** 100 (occupational)  
1000 (residential)

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## Occupational/Residential Risk Assessment - Inhalation

- ❖ Short and intermediate-term
  - ♦ **Study:** Two 90-day inhalation studies
  - ♦ **NOAEL:** 0.1 mg/kg/day – highest dose tested
    - No toxic effects observed at highest dose tested
  - ♦ **Target MOE:** 100 (occupational)  
1000 (residential)

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## Occupational/Residential Risk Assessment - Inhalation

- ❖ Long-term
  - ♦ **Study:** Weight of Evidence Using 5 studies
  - ♦ **Endpoint:** Plasma and RBC cholinesterase inhibition
  - ♦ **NOAEL:** 0.03 mg/kg/day
  - ♦ **LOAEL:** 0.22 mg/kg/day
  - ♦ **Target MOE:** 100 (occupational)  
1000 (residential)
- ♦ **Inhalation Absorption:** 100%

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## CHLORPYRIFOS Dietary Risk Assessments

David Soderberg  
Steve Knizner  
Health Effects Division  
OPP

## Dietary Risk Assessments

### Acute

- ❖ Reflects one-day dietary exposures to pesticide residue

### Chronic

- ❖ Reflects lifetime (long-term) exposures to pesticide residues

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## Dietary Risk Assessments

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$

$$\text{Dietary Exposure} = \text{Consumption} \times \text{Residue}$$

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## Exposure: Consumption

USDA's Continuing Survey of Food Intake by individuals (CSFII) 1989-92 Data

- ❖ One-year surveys designed to measure what Americans eat and drink
- ❖ Represents the general population and subpopulations including infants and children

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## Exposure: Residue

Tier	Residues Data Used
1	Tolerance Level Residues
2	Field Trial Residues
3	Monitoring Data USDA PDP Data FDA Data
4	Market Basket Data

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## Exposure: Residue Data

- ❖ Field trial data
  - ◆ Data used in establishing EPA tolerance levels
    - Used for ~5% of commodities
- ❖ Monitoring Data
  - ◆ USDA's Pesticide Data Program (PDP) data
    - Prepared as in the home (e.g., washing and peeling)
    - Statistically designed for dietary risk assessment
    - Used for ~50% of commodities

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## Exposure: Residue Data

### ❖ Monitoring data (cont.d)

- ◆ FDA Surveillance Monitoring Data
  - Designed for tolerance enforcement
  - Large number of samples and types of food
  - Used for ~40% of commodities

### ◆ Market Basket Data

- DAS National Food Survey
  - 1993-1994
  - 9 Commodities
  - Used for ~10% of commodities

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## Exposure: Residue Data

### ❖ Monitoring data (cont.d)

### ◆ Processing Data

### ◆ Cooking Factors

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## Expression of Dietary Risk

$$RfD = \frac{NOAEL}{UF}$$

$$PAD = \frac{RfD}{FQPA \text{ Safety Factor}}$$

$$\%PAD = \frac{\text{Exposure}}{PAD} \times 100$$

<100% PAD not concern

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## Probabilistic Acute Dietary Analysis Results

Phase 5 Revised Risk Assessment  
Risk Estimates Percent of aPAD\* (99.9<sup>th</sup> Percentile Exposure)

Population	Pre-Mitigation	Post-Mitigation
U.S. Population	16	5
Infants	130	52
Children 1-6	355	82
Children 7-12	258	64
Females	127	40

\*aPAD = 0.0005 mg/kg/day for children and females

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## Chronic Dietary Analysis Results

Phase 5 Revised Risk Assessment  
Risk Estimates as Percent of the cPAD\*

Population	Pre-Mitigation	Post-Mitigation
U.S. Population	4	3
Infants	45	33
Children 1-6	81	51
Children 7-12	59	36
Females	30	20

\*cPAD = 0.00003 mg/kg/day for children and females

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## Major Contributors to Acute Risk

- ❖ Fresh Tomatoes
  - ◆ Mitigation: Delete Use/Remove Tolerance
- ❖ Fresh Grapes
  - ◆ Mitigation: Decrease tolerance from 0.5 to 0.01 ppm
- ❖ Fresh Apples
  - ◆ Mitigation: Decrease tolerance from 1.5 to 0.01 ppm
    - Reflect only pre-bloom application

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## Drinking Water Risk Assessment

- ❖ Conducted because of use pattern and environmental fate profile
- ❖ Available drinking water monitoring limited
- ❖ Drinking water assessment is based on monitoring data and modeling
- ❖ Examined ground and surface water

6/7/00 ❖ Well contamination evaluated separately

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## Drinking Water Risk Assessment

- ❖ Groundwater
  - ◆ Modeling Data
    - SCI-GROW
    - Crops Modeled
      - Sweet corn, cotton, alfalfa, and citrus
    - Model Estimated Environmental Concentrations (EECs) Range from
      - 0.007 ppb (alfalfa) to 0.1 ppb (sweet corn)
    - Monitoring data confirm chlorpyrifos does not impact groundwater

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## Drinking Water Risk Assessment

### ❖ Groundwater

- ◆ Conservative EEC range of 0.007 to 0.1 ppb
- ◆ Acute and chronic exposure
- ◆ Based on modeling data with support from monitoring data
- ◆ Concentration <0.1 ppb for >99% U.S. population

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## Drinking Water Risk Assessment

### ❖ Surface Water

#### ◆ NAWQA Monitoring Data

- More than 3000 samples
- CPY detected at frequencies of:
  - 16% in ag streams (n=1530)
  - 20% in mixed land use streams (n=245)
  - 26% in urban streams in 1997 (n=604)
  - 65% in urban streams from GA, AL, FL, in 1994 (n=57)
- Maximum concentration in surface water was 0.4 ppb
- Majority of detections less than 0.1 ppb
- Data may not represent most vulnerable watersheds

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## Drinking Water Risk Assessment

### ❖ Surface Water

- ◆ Range of 0.026 ppb to 0.4 ppb (95<sup>th</sup>% to maximum) used for acute
- ◆ 0.026 ppb (95<sup>th</sup>%) used for chronic
- ◆ Based on monitoring data

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## Drinking Water Risk Assessment

Allowable Exposure— Food Exposure = Water Exposure

- ❖ Drinking Water Level of Comparison (DWLOC) – surrogate measure of drinking water exposure
- ❖ Compare DWLOC to EEC
- ❖ No concern if EECs less than DWLOC
- ❖ Potential concern if EECs greater than DWLOC

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## Drinking Water Risk Assessment Results

- ❖ There are no acute concerns for residues in drinking water
  - ◆ Acute EECs of 0.007 – 0.4 ppb less than DWLOC of 0.9

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## Drinking Water Risk Assessment Results

- ❖ There are no chronic concerns for residues in drinking water, except possible well contamination
  - ◆ EEC of 0.1 ppb less than DWLOC of 0.14 ppb for ground water
  - ◆ EEC of 0.026 ppb (95<sup>th</sup>%) less than DWLOC of 0.14 ppb for surface water

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## Drinking Water Risk Assessment Uncertainties

- ❖ Drinking water (tap water) data not available
- ❖ EECs do not include dilution from source to tap
- ❖ Treatment may reduce levels
- ❖ EECs highly conservative for majority of U.S. population

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## Drinking Water Risk Assessment

- ❖ Groundwater Impacts of Termiticide Use
  - ◆ Result of well contamination
  - ◆ Highly localized
  - ◆ Wells within 100 feet of treatment
  - ◆ Wells with cracked casing
  - ◆ Low frequency further reduced with implementation of PR-96-7
    - 1997 28.2 per 100,000 homes (pre PR-96-7)
    - 1998 8.3 per 100,000 homes (post PR-96-7)

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# CHLORPYRIFOS

## Occupational/Residential Exposure and Hazard Assessment

Tim Leighton  
Debbie Smegal  
Health Effects Division  
OPP

## Outline of Presentation

- ❖ Agricultural Assessment – Tim Leighton
- ❖ Residential Assessment – Debbie Smegal

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## Agricultural Assessment

- ❖ Handlers
  - ♦ *professional pesticide applicators and farmer/growers who mix, load and apply pesticides*
- ❖ Postapplication Workers
  - ♦ *workers who prune, thin, hoe, prop, scout and harvest crops following pesticide application*

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## Residential Assessment

- ❖ Handler Exposure
  - ♦ Professionals (i.e., lawn care operators)
  - ♦ Homeowners/Residents
- ❖ Postapplication Exposure
  - ♦ Professionals (i.e., golf course maintenance workers)
  - ♦ Homeowners/Residents

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## Agricultural/Residential Risk Assessment - Dermal

### ❖ Short-term exposure

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- ◆ **Endpoint:** Plasma and RBC cholinesterase inhibition
- ◆ **NOAEL:** 5 mg/kg/day
- ◆ **LOAEL:** 10 mg/kg/day
- ◆ **Target MOE:** 100 (occupational)  
1000 (residential)\*

6/7/00

\* Includes the 10X FQPA Safety Factor

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## Agricultural/Residential Risk Assessment - Dermal

### ❖ Intermediate and long-term exposure

- ◆ **Study:** Weight of Evidence using 5 studies
- ◆ **Endpoint:** Plasma and RBC cholinesterase inhibition
- ◆ **NOAEL:** 0.03 mg/kg/day
- ◆ **LOAEL:** 0.22 mg/kg/day
- ◆ **Dermal absorption:** 3% (oral equivalent)
- ◆ **Target MOE:** 100 (occupational)  
1000 (residential)

6/7/00

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## Agricultural/Residential Risk Assessment - Inhalation

### ❖ Short and intermediate-term

- ◆ **Study:** Two 90-day inhalation studies
- ◆ **NOAEL:** 0.1 mg/kg/day – highest dose tested
  - No toxic effects observed at highest dose tested
- ◆ **Target MOE:** 100 (occupational)  
1000 (residential)

6/7/00

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## Agricultural/Residential Risk Assessment - Inhalation

### ❖ Long-term

- ◆ **Study:** Weight of Evidence Using 5 studies
- ◆ **Endpoint:** Plasma and RBC cholinesterase inhibition
- ◆ **NOAEL:** 0.03 mg/kg/day
- ◆ **LOAEL:** 0.22 mg/kg/day
- ◆ **Target MOE:** 100 (occupational)  
1000 (residential)
- ◆ **Inhalation Absorption:** 100%

6/7/00

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## Agricultural Handler Assessment

### Handler Exposure and Risk Calculations

$$\text{Dose} = \frac{(\text{Unit Exposure}) \times (\text{Amount Handled})}{\text{Body Weight}}$$

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Dose (mg/kg/day)}}$$

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## Agricultural Handler Assessment

- ❖ The handler risk assessment is based on
  - ◆ Activity (e.g., mixing/loading)
  - ◆ Formulation and application equipment
  - ◆ Biological monitoring and passive dosimetry studies (five total)
  - ◆ Surrogate data
  - ◆ Amount of pesticide handled
  - ◆ Level of protection (PPE, Engineering Controls)
  - ◆ Toxicity endpoint and uncertainty factors

6/7/00

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## Agricultural Handler Assessment Scenarios

Mixer/Loader	Applicator	Flagger
<ul style="list-style-type: none"><li>◆ Liquids (EC)</li><li>◆ WP (water soluble packets)</li><li>◆ Granulars</li></ul>	<ul style="list-style-type: none"><li>◆ Aerial</li><li>◆ Groundboom</li><li>◆ Airblast</li><li>◆ Tractor-drawn granular spreader</li><li>◆ Hand-held equipment</li></ul>	<ul style="list-style-type: none"><li>◆ Aerial Applications</li></ul>

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## Agricultural Handler Assessment

- ❖ Data Sources
  - ◆ Labels
  - ◆ Use information
  - ◆ Standard values
  - ◆ Five chemical-specific studies
  - ◆ Pesticide Handlers Exposure Database (PHED)

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## Agricultural Handler Assessment

### Five Chemical-Specific Studies

- ❖ Biological monitoring
- ❖ Concurrent passive dosimetry
- ❖ Activities
  - ◆ Mixing/loading liquids for aerial (n=14)
  - ◆ Mixing/loading for groundboom (n=3)
  - ◆ Mixing/loading for airblast (n=15)
  - ◆ Mixing/loading WP for groundboom (n=6)
  - ◆ Groundboom applicator (n=9)
  - ◆ Airblast applicator (n=15)
  - ◆ Mixer/loader/applicator tractor-drawn granular spreader (n=16)
  - ◆ Mixer/loader/applicator backpack (n=2)
  - ◆ Mixer/loader/applicator low pressure handwand (n=1)
  - ◆ Mixer/loader/applicator high pressure handwand (n=13)

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## Biological Monitoring Results

- ❖ Various levels of PPE (e.g., coveralls, gloves, respirator)
- ❖ MOEs
  - ◆ 2 scenarios < 10
  - ◆ 7 scenarios between 10-50
  - ◆ 3 scenarios between 50-100
  - ◆ 2 scenarios > 100

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90

## Agricultural Handler Assessment

### Pesticide Handlers Exposure Database (PHED)

- ❖ Developed by Task Force
- ❖ Monitored exposure data
- ❖ Consistency
- ❖ Widely accepted

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## Agricultural Handler MOE Results

Scenario	MOE ≤ 10	MOE 10 – 50	MOE 50 to 100	MOE ≥ 100
56 Total	2	6	9	39

Various levels of PPE or engineering controls

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## Summary of MOEs of Concern

- ❖ MOEs < 10
  - ◆ Aerial granular (inhalation)
  - ◆ Hand-held sprayer for pine seedling rate
- ❖ MOEs 10 to 50
  - ◆ Mixing/loading wettable powders (aerial)
  - ◆ Hand-held sprayers for greenhouse/nursery
- ❖ MOEs 50 to 100
  - ◆ Closed loading liquid formulation
  - ◆ Aerial sprays (orchard rate)
  - ◆ Airblast (citrus rate)
  - ◆ Backpack (bark treatments)

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## Handler Risk Assessment Summary

- ❖ Some scenarios lack exposure data (e.g., peach root stock dipping, dry bulk fertilizer, seed treatment)
- ❖ Biological Monitoring Results
  - ◆ Many scenarios exceed EPA's level of concern at the level of PPE monitored
  - ◆ Validates the need for engineering controls

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## Handler Assessment - Uncertainties

- ❖ Extrapolate unit exposures to maximum application rates
- ❖ Exposure factors: inhalation rates, physiologically matching body weight to surface area
- ❖ Clothing protection factors (conservative estimates)

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## Agricultural Postapplication Assessment

- ❖ Postapplication risk assessment based on:
  - ◆ Dislodgeable Foliar Residue (DFR):
    - Amount of pesticide residue that "comes off" when contacted by a worker.
  - ◆ Transfer Coefficient (Tc):
    - Indicator of amount of foliar contact by a worker (different for each crop and activity.)
  - ◆ 8 hours worked per day, adult body weight
  - ◆ Exposure duration
    - Short-term (up to 1 month): Accounts for workers rotating into freshly treated fields
    - Intermediate-term (1 to 6 months): Accounts for long harvesting seasons
    - Most sensitive assessment used to calculate REI
  - ◆ Toxicological Endpoint

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## Agricultural Postapplication Assessment

### Exposure and Hazard Calculations

$$\text{Dose} = \frac{\text{DFR} \times \text{Transfer Coefficient} \times \text{Hrs Worked} \times \text{Absorption}}{\text{Body Weight (kg)}}$$

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Dose (mg/kg/day)}}$$

Calculated REI = Day After Treatment When MOE  $\geq$  100

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## Agricultural Postapplication Assessment

### ❖ Sources of Information:

- ◆ Dislodgeable Foliar Residue Data
  - Chemical and crop-specific studies (9 crops)
  - Extrapolating crop-specific studies
- ◆ Transfer coefficients
  - Standard values
  - Chemical-specific studies (scouting, pruning, citrus harvesting)
- ◆ Exposure Factors
  - Standard values (e.g., body weight, hours worked)

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## Agricultural Postapplication Assessment

### ❖ Postapplication exposure scenarios

- ◆ Harvesting fruits and nuts from trees
- ◆ Harvesting field crops
- ◆ Scouting, pruning, or other non-harvesting activities

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## Agricultural Postapplication Assessment

### ❖ Time When Calculated Restricted-Entry Intervals (REIs) Result in MOEs > 100

Crops	Scouting	Harvesting	PHI
All Crops (except as noted)	24 hours	24 hours (48 hours sweet potatoes)	Min. 7 days (peppers)
Cauliflower	3 days	10 days	EC 30 days WP 21 days
Citrus	2 days	5 days	21 to 35 days
Nut Trees	2 days	2 days	Min. 14 days
Fruit Trees	1 day	4 days	28 days

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100

## Agricultural Postapplication Assessment

### Uncertainties

- ❖ Lack of exposure data – spray drift, soil incorporated treatments
- ❖ Transfer Coefficients
- ❖ Extrapolating DFR from crop to crop
- ❖ Application timing (early season for some crops) and lengthy PHIs
- ❖ Exposure Factors

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## Agricultural Incidents

- ❖ California 1982-1992; 210 agricultural cases involving chlorpyrifos, 100 cases where it was primarily responsible
  - ◆ Mainly handlers – 51 %. Drift incidents (35%, half due to one incident) occur
- ❖ Rate of systemic incidents per 1000 applications in California range from 0 to 0.55, consistent with median of 0.41 for 28 insecticide alternatives

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## CHLORPYRIFOS Residential Exposure Assessment

Debbie Smegal  
Health Effects Division

## Residential Exposure Assessment

- ❖ Handler Exposure
  - ◆ Professionals (e.g., lawn care operators)
  - ◆ Homeowners/Residents
- ❖ Postapplication Exposure
  - ◆ Professionals (e.g., golf course maintenance workers)
  - ◆ Homeowners/Residents (e.g., golfer, toddler on treated lawns)

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## Residential Exposure Assessment (Professionals and Homeowners)

### ❖ Data Sources:

- ◆ Registered labels
- ◆ Use information
- ◆ Chemical-specific studies
- ◆ Pesticide Handlers Exposure Database (PHED)
- ◆ Residential Standard Operating Procedures (SOPs)

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## Residential SOPs

- ❖ Screening level methodology
- ❖ Updated assumptions based on Scientific Advisory Panel (SAP) comments
- ❖ Used to assess 7 of 9 homeowner handler scenarios
- ❖ Used to assess 5 of 9 postapplication scenarios

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## Residential Exposure Assessment

### ❖ Nine chemical-specific exposure studies

Used to assess

- ◆ 4 out of 10 professional handler scenarios
- ◆ 1 out of 9 homeowner handler scenarios
- ◆ 4 out of 9 postapplication scenarios

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## Residential Exposure Assessment

Mixer/Loader	Applicator	Postapplication
<ul style="list-style-type: none"> <li>◆ Liquids</li> <li>◆ WP (water soluble packets)</li> <li>◆ Granulars</li> </ul>	<ul style="list-style-type: none"> <li>◆ Push type spreader</li> <li>◆ Belly grinder</li> <li>◆ Hand</li> <li>◆ Sprinkler can</li> <li>◆ Hand held sprayer</li> <li>◆ Aerosol can</li> <li>◆ Aerial</li> <li>◆ Groundboom</li> </ul>	<ul style="list-style-type: none"> <li>◆ Liquids</li> <li>◆ Granulars</li> <li>◆ Pet collars</li> <li>◆ Dust</li> </ul>

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## Professional/Homeowner Handler Assessment

### Scenarios Evaluated:

- ❖ Liquid Turf Treatment
- ❖ Granular Turf Treatment
  - ◆ Push-type spreader
  - ◆ Belly grinder
  - ◆ Hand
- ❖ Indoor Crack, Crevice and Spot Treatment
- ❖ Insecticidal Dust Application

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## Professional/Homeowner Handler Assessment (cont.d)

- ❖ Termiticide Treatment (professional)
- ❖ Golf Course Treatment (professional)
- ❖ Mosquitocide Application (professional)
- ❖ Paintbrush Application (homeowner)

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## Professional/Homeowner Handler Assessment

- ❖ Evaluated minimum, typical and maximum rates
- ❖ Dermal and inhalation exposure
- ❖ Short, intermediate and long-term (professional)
- ❖ Short-term (homeowner)

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## Professional Handler Results

- ❖ All MOEs less than 100 except
  - ◆ Mosquito abatement professionals
  - ◆ Golf course workers

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## Homeowner Handler Results

- ❖ All scenarios result in MOEs less than 1000 except
  - ◆ Limited crack and crevice spot treatment (2 oz of 0.5% material)

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## Postapplication Professional Assessment

- ❖ Golf course maintenance workers
  - ◆ MOEs greater than 100

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## Postapplication Residential Assessment

Evaluated nine scenarios:

- ❖ Turf Treatment (liquid, granular)
- ❖ Yard and Ornamental Sprays
- ❖ Golf Course Use
- ❖ Indoor Crack, and Crevice
- ❖ Post Construction Termiticide Treatment
- ❖ Pet Collar Uses
- ❖ Mosquitocide Abatement Use
- ❖ Perimeter Treatment of Residence

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## Postapplication Residential Results

- ❖ All MOEs less than 1000 except
  - ◆ Mosquito abatement use
  - ◆ Golf course use

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## Termiticide Postapplication Data

- ❖ DAS air monitoring study for 31 homes
- ❖ Air concentrations measured in kitchen, bedroom, and basement
- ❖ Four types of homes assessed: basement, slab, crawlspace, and plenum
- ❖ Applications conducted according to current label at 1%

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## Termiticide Postapplication Assumptions

- ❖ Inhalation exposure of primary concern
- ❖ Calculated incremental time weighted average air concentrations
- ❖ Air concentrations normalized to 0.5% ai
  - ◆ To assess mitigation
- ❖ Evaluated both 90 day and 1 year durations due to uncertainties in toxicity endpoints

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## Residential Risk Postapplication

### Termiticide Use MOEs for Children 1-6

Home Type	Range of MOEs 90-Day TWA	Range of MOEs 1-Year TWA
Basement	600 - 8700 (median = 3800)	270 - 2500 (median = 1100)
Crawlspace	950 - 7200 (median = 2100)	340 - 2100 (median = 530)
Slab	440 - 5800 (median = 1900)	280 - 2200 (median = 600)
Plenum	460 - 6400 (median = 1900)	270 - 2700 (median = 760)

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## Uncertainties in Risk Assessment

There are uncertainties associated with

- ❖ Endpoint Selection
  - ◆ Short exposure time (6 hours day/5 days per week)
  - ◆ Route-to-route extrapolation
  - ◆ True no observed adverse effect level may be higher
- ❖ Chlorpyrifos Air Concentration Data
  - ◆ Houses from warm climates may overestimate homes in temperate climates
- ❖ Exposure Assumptions
  - ◆ Child at home 20 hr/day, 7 days/week for up to 1 year

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## Residential Risk Postapplication

### Termiticide Use MOEs for Children 1-6

Home Type	Range of MOEs 90-Day TWA	Range of MOEs 1-Year TWA
Basement	600 - 8700 (median = 3800)	270 - 2500 (median = 1100)
Crawlspace	950 - 7200 (median = 2100)	340 - 2100 (median = 530)
Slab	440 - 5800 (median = 1900)	280 - 2200 (median = 600)
Plenum	460 - 6400 (median = 1900)	270 - 2700 (median = 760)

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## Termiticide Assessment Conclusions

Adverse effects unlikely:

- ❖ Conservative assumptions
- ❖ 1000-fold Safety Factor
- ❖ Additional 3 to 10-fold cushion between effect level and no effect level in animal studies
- ❖ Mitigation measures

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## Residential Incidents

- ❖ Rate of exposure incidents comparable to other OPs
- ❖ Most (92%) reported minor effects (e.g., headaches, nausea)
- ❖ Data suggest that exposure to concentrates can lead to more severe effects than ready-to-use formulations or other non-OP pesticides especially in children. Most of these incidents are due to misuse
- ❖ Poison Control Center (PCC) data 1993-1996 shows 51% of exposures reported were children < six years old

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## Residential Incidents

- ❖ DAS initiated a 10-point plan in 1997 to address incidents
- ❖ 25% of PCC incidents were related to uses that were cancelled by the 10-point plan
- ❖ Recent study of chlorpyrifos applicators (NIOSH) did not find evidence of chronic neurobehavioral effects, except in a subset of poisoned workers
- ❖ 98% of exposures are due to products removed under the risk mitigation plan

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## Aggregate Risk Assessment

- ❖ Includes exposure from various sources
  - ◆ Food
  - ◆ Drinking water
  - ◆ Residential and Recreational Uses
- ❖ Both adults and children considered

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## Aggregate Risk Assessment

Based on use changes reflecting mitigation measures

- ❖ Acute aggregate does not exceed level of concern
  - ◆ Food – highly refined
  - ◆ Water – unrefined
- ❖ Short-term aggregate risk does not exceed level of concern
  - ◆ Food – highly refined
  - ◆ Water – unrefined
  - ◆ Residential – conservative
    - Golfers - mosquitocide

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## Aggregate Risk Assessment

Based on changes reflecting mitigation measures

- ❖ Chronic aggregate risk does not raise a concern
  - ◆ Food – highly refined
  - ◆ Water – unrefined
  - ◆ Residential – mitigation should reduce exposure

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## TCP Assessment Toxicity/Risk of TCP

- ❖ TCP less toxic than parent chlorpyrifos
- ❖ Risk assessments for chlorpyrifos are protective of possible effects from TCP

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## TCP Assessment

### Major Sources of TCP Exposures

#### SOURCES OF TCP:

- ❖ Chlorpyrifos 20,000,000 lbs/ai/yr
  - ❖ Chlorpyrifos-methyl 90,000 lbs/ai/yr
  - ❖ Triclorpyr 1,000,000 lbs/ai/yr
- ❖ Numerous studies show low levels of TCP in the urine of 77-100% of subjects tested

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## Environmental Fate and Effects Assessment

Daniel Rieder  
Biologist  
Environmental Fate and Effects Division  
OPP

## Environmental Fate and Effects Assessments

- ❖ Environmental Fate Assessment
  - ◆ Lab and Field Studies (Characterize Persistence, Mobility, & Bioaccumulation)
- ❖ Water Resources Assessment
  - ◆ Modeling and Monitoring (Estimate Potential Exposure)
- ❖ Ecological Toxicity
  - ◆ Acute and Chronic Tests (Determine Toxicity to Terrestrial and Aquatic Organisms)
  - ◆ Terrestrial and Aquatic Field Studies (Determine Toxic Effects in Field)

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## Ecological Risk Assessment: (Deterministic)

- ❖ Compare exposure estimates to ecological toxicity to determine potential effects
- ❖ Calculate risk quotient:  $\frac{EEC}{TOX} = RQ$
- ❖  $RQ > LOC$  suggests potential risk
- ❖ Intentionally conservative (accounts for wide ranges of variability)

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## Risk Characterization

- ❖ Refines the Tier 1 Deterministic Assessment
  - ◆ Begins with the deterministic assessment but goes further
  - ◆ Considers other information such as fate, and extent of usage
  - ◆ Compares exposure estimates to field study residue data
  - ◆ Biomonitoring data used to verify acute effects
  - ◆ Compare predicted effects with incidents

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## Laboratory Fate Data

- ❖ Breakdown by water (hydrolysis)
  - ◆ Half-life 73 days (neutral and acidic conditions)
  - ◆ Half-life 16 days (alkaline conditions)
- ❖ Breakdown in light (photolysis) half-life 30 days
- ❖ Aerobic soil half-lives range from 11 to 180 days in 8 soils

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## Laboratory Fate Data

- ❖ Anaerobic soil half-lives are 39 and 51 days in two soils
- ❖ Binds readily to soil (Kd values: 50 to 260)
- ❖ Bioaccumulates in aquatic organisms:
  - ◆ Residues in tissues decline rapidly in clean water
- ❖ Primary degradate: TCP 3,5, 6- trichloro-2-pyridinol

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## TCP Laboratory Fate Data

- ❖ Highly soluble (500 mg/L) and mobile (Koc of 136)
- ❖ Breaks down in light (half-life 1 day)
- ❖ Breaks down rapidly via soil photodegradation (half-life 8 hours)
- ❖ Does not breakdown in water (hydrolysis)
- ❖ Does not metabolize under aerobic or anaerobic conditions

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## Field Dissipation

- ❖ Terrestrial field half-lives under 60 days
- ❖ No leaching observed in the field
- ❖ Degradate TCP very mobile in soil

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## Toxicity to Terrestrial Organisms

- ❖ Birds
  - ♦ Moderately to very highly toxic
  - ♦ Reproductive effects
    - Reduction in number of eggs laid
    - Reduction in adult body weight
- ❖ Mammals
  - ♦ Slightly to highly toxic
  - ♦ Reproductive effects
    - Reduction in pup weight
    - Increase in pup mortality
- ❖ Bees
  - ♦ Highly toxic
    - Short-term residual toxicity at 1 lb/A

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## Toxicity to Aquatic Organisms

- ❖ Fish: Freshwater and Estuarine
  - ♦ Moderately to very highly toxic
  - ♦ Reproductive effects
    - Reduction in number of young
- ❖ Invertebrates: Freshwater and Estuarine
  - ♦ Very highly toxic to crustaceans and oyster growth (shell deposition)
  - ♦ Moderately to oyster larvae
  - ♦ Reproductive effects
    - Reduction in number of young

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## TCP (Degradate) Toxicity

- ❖ Acute toxicity
  - ♦ Birds
    - Practically non-toxic
  - ♦ Mammals
    - Slightly to moderately toxic
    - No reproduction test
  - ♦ Fish
    - Slightly to moderately toxic
  - ♦ Invertebrates
    - Slightly to moderately toxic
- ❖ Chronic toxicity
  - ♦ No data

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## Terrestrial Risk Overview

- ❖ The Agency concludes potentially high risk of acute and chronic effects
  - ◆ Mammals
  - ◆ Birds
- ❖ Based on screening level assessment and results of field testing

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## Terrestrial Risk (Field Studies)

- ❖ Three terrestrial field studies
  - ◆ Field corn in Iowa (granular and spray)
  - ◆ Orange groves in California (spray blast)
  - ◆ Golf courses in central Florida (granular and spray)

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## Terrestrial Risk (Field Studies)

- ❖ Adverse effects in these field studies
  - ◆ Wildlife effects on treated sites (chlorpyrifos detected in tissue)
    - small mammals
    - birds
    - an aquatic turtle
    - snakes (secondary toxicity assumed)
    - adult toads
    - adults frogs
    - tadpoles

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## Terrestrial Risk (Field Studies)

Measured Concentrations in Iowa Corn Field 4 EC Spray Study Confirm EECs

Application	Use rate Lbs ai/A	Measured Crop Foliage Residues (ppm)	Nomograph Based Max. EECs Crop foliage (ppm)
1 <sup>st</sup>	3.0	N/A (preplant)	No Foliage
2 <sup>nd</sup>	1.5	136 to 544	203
3 <sup>rd</sup>	1.5	90 to 417	Not Calculated
4 <sup>th</sup>	1.5	23 to 256	266

Lowest Avian LC50 136 ppm and Mammalian herbivores LC50s 102-647 ppm

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## Terrestrial Risk (Incidents)

- ❖ Terrestrial incidents have been reported
- ❖ Wide variety of species affected
  - Birds
  - Mammals
  - Reptiles
- ◆ Uses related to incidents
  - Most incidents – termiticide uses
  - Agricultural crops
  - Turf uses
- ◆ Reported incidents are highest in areas of high human activity

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## Aquatic Risk (Summary)

- ❖ Aquatic risk assessed using refined models when possible
- ❖ Field monitoring and field bioassay data considered
- ❖ Based on modeled EECs
  - ◆ Acute risk potential is high for
    - Aquatic invertebrates
    - Fish
  - ◆ Chronic risk potential
    - High for aquatic invertebrates
    - High for fish in some scenarios
- ❖ Risk potential supported by field studies and biomonitoring data
  - ◆ Measured residues exceed acute toxicity for aquatic invertebrates and fish
  - ◆ Biomonitoring indicates adverse effects from chlorpyrifos
- ❖ Risk potential supported by incident reports

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## Aquatic Risk (Field Studies)

Agency compared measured aquatic concentration with toxicity

- ❖ Field studies with pond measurements
  - ◆ Iowa corn, spray and granular
  - ◆ California citrus, spray blast
  - ◆ Florida golf course, granular and spray

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## Aquatic Risk (Field Studies)

Measured Water Concentrations in Iowa Corn Field Studies  
Spray Formulation

4 EC Application	Use Rate Lbs ai/A	Measured Water Concentration (ppb)	Modeled Water Concentration (ppb)
1 <sup>st</sup>	3.0	< 1 to 6.32	11
2 <sup>nd</sup>	1.5	< 1 to 115	7.7
3 <sup>rd</sup>	1.5	No data	Not Calculated
4 <sup>th</sup>	1.5	< 1 to 2.20	24

- Level of detection = 1 ppb
- Lowest Fish LC50 1.8 ppb and Aquatic Invertebrate EC50 0.1 ppb
- No reported fish kills

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## Aquatic Risk (Field Studies)

Measured Water Concentrations in Iowa Corn Field Studies  
Granular Formulation

15 G Application	Use Rate Lbs ai/A	Water Concentration (ppb)	Estimated Water Concentration (ppb)
1 <sup>st</sup>	3.0	< 1	8.6
2 <sup>nd</sup>	1.0	No data	3.2
3 <sup>rd</sup>	1.0	< 1 to 1.81	6.4

- Level of detection = 1 ppb
- Lowest Fish LC50 1.8 ppb and Aquatic Invertebrate EC50 0.1 ppb
- No reported fish kills
- Granular applications resulted in lower water concentrations

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## Aquatic Risk (Field Studies)

Measured Water Concentrations in Ponds: California Citrus Field Studies  
Airblast

Application	Use Rate Lbs ai/A	Water Concentration (ppb)	Estimated Water Concentration (ppb)
1 <sup>st</sup>	1.5	< 1	7.64
2 <sup>nd</sup>	6.0	< 1 to 486	27.6
1 <sup>st</sup>	3.5	< 1 to 1.04	18.02
2 <sup>nd</sup>	4.0	< 1 to 2.27	29.7

- Level of detection = 1 ppb
- Lowest Fish LC50 1.8 ppb and Aquatic Invertebrate EC50 0.1 ppb
- Dead fish were found in ponds adjacent to groves on several occasions

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## Aquatic Risk (Field Studies)

Measured Water Concentrations in Florida Golf Course Field Studies

4 EC Application	Use Rate Lbs ai/A	Water Concentration (ppb)	Estimated Water Concentration (ppb)
1 <sup>st</sup>	4.0	< 1	14.75
2 <sup>nd</sup>	4.0	< 1	29.03
15 G Application	Use Rate Lbs ai/A	Water Concentration (ppb)	Estimated Water Concentration (ppb)
1 <sup>st</sup>	4.0	< 1	13.28
2 <sup>nd</sup>	4.0	< 1 to 2.55	25.31

- Level of detection = 1 ppb
- Lowest Fish LC50 1.8 ppb and Aquatic Invertebrate EC50 0.1 ppb
- On several occasions dead fish found in water hazards some in study area
- Other fish kills occurred outside of the study area

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## Aquatic Risk (Field Studies)

Conclusion and evaluation of measured residues in field studies

- ❖ Highly variable, often less than modeled value, occasionally higher
- ❖ Sometimes measured residues exceed critical toxicity thresholds

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## Aquatic Risk (Incidents)

- ❖ Aquatic incidents reported
  - ◆ Wide variety of species affected
    - Fish (usually large numbers killed)
    - Invertebrates
    - amphibians
  - ◆ Uses related to incident
    - Termiticide uses – most incidents
    - Agricultural crops
    - Turf uses
  - ◆ Reported incidents highest in high human activity areas

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## Aquatic Risk (Termiticide Use)

- ❖ Aquatic risks not modeled
- ❖ Highest number of reported incidents of any use
- ❖ Surface water incidents reported by Dow
  - ◆ 1997 – 7.2 per 100,000 structures
  - ◆ 1998 – 4.3 per 100,000 structures

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## Aquatic Risk Sources of Exposure Identified In Biomonitoring Data

- ❖ Biomonitoring studies have identified a wide range of sources of surface water exposure
  - ◆ Termiticide uses
  - ◆ Agricultural runoff
  - ◆ Homeowner uses on lawns, gardens, ornamentals, etc.
  - ◆ Commercial nurseries (trees and ornamentals)
  - ◆ Cleaning of equipment

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## Aquatic Risk (Biomonitoring)

- ❖ Biomonitoring studies show lethal effects on *Ceriodaphnia*
  - ◆ In rainfall in the Sacramento Area
  - ◆ In storm sewer discharges in California urban areas
  - ◆ In POTW effluents from home uses, cleaning equipment, etc.
  - ◆ In streams and rivers

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## Aquatic Risk (Biomonitoring)

### Examples of biomonitoring data

- ❖ Biomonitoring studies show lethal effects on *Ceriodaphnia*
  - ◆ Along 43 miles of the San Joaquin River
    - 50% of samples showed lethal effects
- ❖ Biomonitoring studies show lethal effects on *Ceriodaphnia*
  - ◆ In the upper Newport Bay drainage area, San Diego
    - Homeowner uses
    - Nurseries
- ❖ Biomonitoring studies show lethal effects on mysid shrimp
  - ◆ In the lower reaches of the Newport drainage area

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## Risk Characterization

### ❖ Chlorpyrifos uses

- ◆ Pose risks to a broad spectrum of fish and wildlife species
- ◆ Agricultural uses
  - Potentially high risk quotients for fish and wildlife
  - Field studies showed:
    - Exposures exceeding terrestrial and aquatic toxicity
    - Effects seen on all vertebrate classes
    - Incidents of mortality to terrestrial and aquatic species reported

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## Risk Characterization (cont.d)

### ❖ Termiticide use

- ◆ Associated with reported fish kills in EPA Incident Data System
  - Of all uses, had highest number of terrestrial incidents
- ❖ Biomonitoring data indicate widespread aquatic toxicity
  - ◆ In agriculture and urban areas

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## Comments on Risk Assessments

- ❖ Dow has submitted probabilistic assessments
- ❖ General Agency response:
  - ◆ Many factors to consider that affect exposure and effects distributions
  - ◆ Currently reviewing to determine applicability

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## Risk Summary and Next Steps

Lois Rossi, Director  
Special Review and Reregistration Division  
OPP

## Dietary Risk Mitigation

### ❖ Mitigation

- ◆ Restrict apple use to pre-bloom
- ◆ Reduce apple tolerance to 0.01 ppm
- ◆ Eliminate tomato use/remove tolerance
- ◆ Reduce grape tolerance to 0.01 ppm

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## Mitigated Risks - Dietary

Effect of Mitigation

Risk Estimate as % PAD

Population Subgroup	% aPAD	% cPAD
U.S. Population	5	3
Infants	52	33
Children (1-6 years old)	82	51
Children (7-12 years old)	64	36
Females	40	20

❖ Aggregate dietary risk (food and water) not of concern

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## Non-Termiticide Risk Mitigation

### ❖ For Residential Non-Termiticide Uses

- ◆ All uses removed except golf courses, containerized baits, and two public health uses (mosquitocide and fire ant mounds)

### ❖ For Other Non-Termiticide Uses

- ◆ All uses removed except limited use in industrial settings

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## Mitigated Risks – Non-Termiticide

### ❖ Effects of Mitigation

- ◆ Eliminate exposures and risks of concern for children
- ◆ Exposure to residents from mosquitoicide, containerized baits, and fire ant use not of concern
- ◆ Reducing application rate provides adequate MOEs for golfers
- ◆ Removal of most outdoor uses reduces water exposure in urban areas

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## Termiticide Risk Mitigation

### ❖ For Termiticide Uses

- ◆ Reduce application rate to 0.5%
- ◆ Whole house post-construction removed
- ◆ Limited spot and local post-construction use phased out (by 2002)
- ◆ Pre-construction use phased out (by 2005)

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## Mitigated Risks - Termiticide

- ❖ With mitigation, these exposures do not raise a concern
- ❖ The use with exposure of most concern (whole house barrier treatment) removed
- ❖ Exposure/risk from limited local and spot treatment and pre-construction treatment expected to be less

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## Mitigated Risks - Aggregate

- ❖ Acute and short-term aggregate risks are not of concern
- ❖ Chronic aggregate risks with all uncertainties and mitigation considered do not raise a concern

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## Summary of Mitigation - Worker

- ❖ Agreed to REIs:

Crops	Harvesting REIs	PHI
All Crops (except as noted below)	24 hours (48 hours sweet potatoes)	Min. 7 days (peppers)
Cauliflower	10 days	EC 30 days WP 21 days
Citrus	5 days	21 to 35 days
Nut Trees	2 days	Min. 14 days
Fruit Trees	4 days	28 days

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## Mitigated Risks - Worker

- ❖ Agreed to REIs address reentry worker risk concerns
- ❖ Risks to mixers, loaders, and applicators still require mitigation

Scenario	MOE $\leq 10$	MOE 10 – 50	MOE 50 to 100	MOE $\geq 100$
56 Total	2	6	9	39

Various levels of PPE or engineering controls

- ❖ Involve stakeholders

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## Summary of Risks - Ecological

- ❖ Acute and reproductive risks to many non-target aquatic and terrestrial organisms
- ❖ In general, greatest concern is for aquatic organisms

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## Summary of Mitigation - Ecological

- ❖ Removal of most outdoor uses mitigates water exposure in urban areas as well as many exposures to terrestrial organisms
- ❖ Risk mitigation still necessary for other concerns
  - ◆ Decrease application rates
  - ◆ Decrease number of applications
  - ◆ Increase application intervals
  - ◆ Involve stakeholders

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## Public Comment

- ❖ Public participation will allow comments
  - ◆ Focus on remaining issues – worker and ecological risk mitigation
  - ◆ 6f process for cancelled uses

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## Next Steps

- ❖ 60-day public comment period
- ❖ E-mail comments to:
  - ◆ [opp-docket@epa.gov](mailto:opp-docket@epa.gov)
- ❖ Mail comments to:
  - U.S. EPA
  - OP Pesticide Docket (7502C)
  - 401 M St. SW
  - Washington, DC 20460

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## Contacts

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